

## **Remarks**

Non-elected claims 4-10 and 14-17 have been cancelled without prejudice to, or disclaimer of, the underlying subject matter. Claims 1, 2, 12 and 29 have been amended to facilitate prosecution. Claims 30-33 have been added. Upon entry of the foregoing amendments, claims 1-3, 11-13, 29 and 30-33 are pending. No new matter has been added by these amendments. Support for the foregoing amendments may be found in the sequence listing, in the original claims, the figures, and throughout the specification. *See, e.g.,* specification at page 2, lines 11-13; page 13, lines 6-15; page 19, line 6 through page 21, line 31; Example 8; and Examples 10 - 12.

### ***I. Objection to the specification – sequence rules***

The Office requested that Applicants amend the application to comply with the requirements of 37 C.F.R. § 1.821-1.825. Office Action at page 2. Applicants have amended the sequence listing and the specification in order to comply with 37 C.F.R. § 1.821-1.825. No new matter enters by these amendments. Support for these amendments can be found in the sequence listing, the figures, and throughout the specification.

### ***II. Restriction Requirement***

Applicants respectfully maintain that the restriction of claims 1-17 is improper. The Office alleges that the restriction of claims 7-10 and 14-17 remains proper because “the methods of Groups I-II are drawn to unique DNA compositions of discrete function.” Office Action at page 2. However, the Office has submitted no proof that an undue burden would be imposed by a search and examination of the entire application, including claims 7-10 and 14-17. Applicants respectfully reiterate that the complete examination of the application would be handled most expeditiously by treating all of the pending claims as a single entity. To facilitate prosecution, however, Applicants have elected claims 1-6, 11-13, and 29 and acknowledge that the restriction requirement is

made final. As such, non-elected claims 7-10 and 14-17 have been cancelled without prejudice to, or disclaimer of, the underlying subject matter.

### ***III. Objection to the priority claim***

The Office alleges that “[t]he instant application is drawn to a polynucleotide encoding a polypeptide having a  $\beta$ -ketoacyl-CoA synthase activity, which was first disclosed in parent application 08/265,047 filed 06/23/1994 now issued U.S. Patent 5,679,881.” Applicants respectfully disagree. Applicants bring to the Examiner’s attention that SEQ ID NOs.: 4 and 6 of the instant application, which encode jojoba polypeptides having  $\beta$ -ketoacyl-CoA synthase activity, were disclosed as SEQ ID NOs.: 10 and 11 (Figures 2 and 3), respectively, of the application corresponding to USSN 08/066,299, filed May 20, 1993. Applicants further submit that SEQ ID NOs.: 4 and 6 of the instant application were also disclosed as SEQ ID NOs. 2 and 3, respectively, in U. S. Application No. 08/160,602, filed November 30, 1993, now abandoned. Therefore, Applicants respectfully submit that the correct priority date of the claimed invention is no later than May 20, 1993.

### ***IV. Rejections under 35 U.S.C. §112, first Paragraph, Written Description***

Claims 1-6, 11-13, and 29 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. Office Action at page 3. The Office further alleges that “[a]pplicant does not describe any other very long chain fatty acid molecule-altering DNA sequences other than a polynucleotide encoding a jojoba  $\beta$ -ketoacyl-CoA synthase condensing enzyme (page 8, Table 8 refers to figure 3), and the putative CE15 and CE20 cDNA. Given the claim breadth and lack of guidance as discussed above, the specification does not provide an adequate written description of the claimed invention.” Office Action at page 4. Applicants respectfully disagree.

The purpose of the written description requirement is simply to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not “describe,” in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989).

A related and equally well-established principle of patent law is that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), quoting *In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, simply because the claimed nucleic acid sequences may also include sequences from other species does not require that Applicants describe each and every one of these molecules.

Applicants have provided detailed chemical structures, *i.e.*, nucleic acid sequences from *jojoba*, *Brassica*, *Arabidopsis*, *Lunaria*, and *Nasturtium*, including SEQ ID NOs: 3, 5, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, and 29. These sequences provide “structural feature[] possessed by members of the [claimed] genus that distinguish[] them from others.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Accordingly, in the present case, Applicants have provided detailed chemical structures in contrast to the mere name cDNA provided in *Eli Lilly*. Therefore, the present claims meet the written description provision under 35 U.S.C. § 112, first paragraph.

Applicants respectfully submit that functionality is not necessarily a requisite component to fulfilling written description. Nevertheless, as acknowledged by the Office, Applicants demonstrate that the *jojoba* plant sequences of SEQ ID NO: 3 and SEQ ID NO: 5 encode proteins with  $\beta$ -ketoacyl-CoA synthase activity. Office Action at

page 3. The  $\beta$ -ketoacyl-CoA synthase protein was purified from jojoba, its nucleic acid sequence was determined and its activity confirmed by assays as described in the specification. *See, e.g.*, specification at page 38, lines 3-35; and Examples 11-12. Other DNA sequences, including SEQ ID NOs: 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, and 29 were similarly identified by sequence homology as encoding  $\beta$ -ketoacyl-CoA synthases. Therefore, Applicants have provided evidence that the disclosed sequences are indeed  $\beta$ -ketoacyl-CoA synthases. In addition, Applicants have presented a clearly defined chromatographic method for analysis of  $\beta$ -ketoacyl-CoA synthase activity in plants, as well as a method for confirming that transgenic expression of  $\beta$ -ketoacyl-CoA synthase in plants results in increased VLCFA production. *See, e.g.*, Examples 11 and 12. Accordingly, Applicants respectfully submit that a person of ordinary skill in the art would recognize that the specification provides a description of the invention defined by the claims.

Although Applicants disagree that the specification as filed does not satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, in order to facilitate prosecution, Applicants have amended claims 1, 2, and 29, and cancelled non-elected claims 4-6. Applicants therefore submit that the grounds for the rejection of claims 1-6, 11-13, and 29 has been rendered moot. In light of these remarks, Applicants respectfully request withdrawal of these rejections.

***V. Rejections under 35 U.S.C. § 112, first Paragraph, Enablement***

Claims 1-6, 11-13, and 29 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Office Action at page 5. Applicants respectfully disagree.

Applicants thank the Examiner for acknowledging that the specification is “enabling for production of 24:1 VLCFA from above 5% to 7.8% of weight in seeds of canola transformed with a polynucleotide encoding jojoba  $\beta$ -ketoacyl-CoA synthase

condensing enzyme.” Office Action at page 5. Applicants respectfully disagree, however, that the specification “does not reasonably provide enablement for production of 24:1 VLCFA above 5% or 7% in any ... plant [other than canola] using any ... very long chain fatty acid molecule-altering DNA sequences [other than a jojoba  $\beta$ -ketoacyl-CoA synthase].”

It is well-established law that “the enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Applicants further submit that disclosure of a single species provides sufficient enabling support if one of skill in the art can, using the state of the art and Applicant’s written disclosures, practice the invention in its full scope without undue experimentation.<sup>1</sup> *See In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988) (Applicant’s specification provided sufficient enabling support for the applicant’s claim to immunoassay methods using a generic class of antibodies even though applicant made a public deposit of only a single hybridoma cell line that secreted a specific antibody.)

The claimed invention is clearly enabled by the present specification. As acknowledged by the Examiner, the specification discloses purification of the  $\beta$ -ketoacyl-CoA synthase protein from jojoba and confirmation of its activity by demonstration that plants transformed with the  $\beta$ -ketoacyl-CoA synthase have increased VLCFA levels. *See, e.g.*, specification at page 38, lines 3- 35 and Example 11. The specification also describes a TLC assay for measuring the activity of  $\beta$ -ketoacyl-CoA synthase. *See, e.g.*, Example 12.

One of skill in the art would be able to readily use the techniques described in the specification for plant transformation and chromatographic assays of plant seeds, to measure the VLCFA levels in plants transgenic for one of the disclosed  $\beta$ -ketoacyl-CoA

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<sup>1</sup> Applicants note that the performance of routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (CCPA 1976). Time and difficulty of experiments are not determinative if they are merely routine. MPEP § 2164.06, page 2100-186.

synthases. Although preparation and assaying of such transformed plants *might or might not* require a substantial amount of experimentation, such experimentation is not “undue experimentation” because the methods needed to practice the invention were well known, and there is a high level of skill in this art. *See* footnote 1 *infra*. It is established patent jurisprudence that Applicants need not teach “conventional and well-known genetic engineering techniques.” *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000). Furthermore, the performance of routine and well-known steps, such as, *e.g.*, an assay to confirm changes in VLCFA levels, cannot create undue experimentation even if it is laborious. *See In re Wands*, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404; *In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). For at least these reasons, Applicants are not relying solely on sequence identity data to infer function, as the Office suggests.

Applicants next address the Office’s assertion that the specification “does not reasonably provide enablement for production of 24:1 VLCFA above 5% or 7% in any ... plant [other than canola] using any ... very long chain fatty acid molecule-altering DNA sequences [other than a jojoba  $\beta$ -ketoacyl-CoA synthase].” Applicants respectfully submit that the specification demonstrates that transgenic expression of jojoba  $\beta$ -ketoacyl-CoA synthase is associated with elevated levels of very long chain fatty acids, relative to native levels, in canola (Table 4), HEAR (Table 5), *Arabidopsis* (Table 6), and *Brassica* LEAR (Table 7). The specification further provides that “[a]nalysis of T3 seed oil from LEAR plants transformed with the jojoba CE shows that up to 7.8% of the seed oil is 24:1.” *See, e.g.*, specification at page 74, lines 1-3. “In plants that do accumulate VLCFA, pCGN7626 shifts the fatty acid composition towards longer VLCFA.” *See, e.g.*, specification at page 74, lines 10-12.

Although Applicants disagree that the specification as filed does not satisfy the enablement requirement under 35 U.S.C. §112, first paragraph, in order to facilitate prosecution, Applicants have amended claims 1, 2, and 29, and cancelled non-elected claims 4-6. Applicants therefore submit that the grounds for the rejection of Claims 1-6, 11-13, and 29 under 35 U.S.C. §112, first paragraph has been rendered moot. In light of these remarks, Applicants respectfully request withdrawal of these rejections.

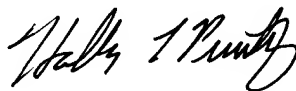
**VI. Double Patenting Rejection**

Claims 1-6, 11-13 and 29 stand rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 5,679,881. Applicants reserve their right to traverse or file a terminal disclaimer at a later time upon indication of allowable subject matter.

**Conclusion**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5068 should any additional information be necessary for allowance.

Respectfully submitted,



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